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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,116	POISSONNIER-DURIEUX ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22-33,35 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22-33,35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Comment [j1]: Also insert what the homology is between the prior art and the instant claims. Do not cite In re Henze.

DETAILED ACTION

Claims 20, 22-33, 35 and 37 are currently pending in the instant application. Applicants have amended claim 1 and cancelled claim 36 in an amendment filed on February 4, 2008. The Examiner has withdrawn the finality of the last Office Action mailed October 31, 2007. Upon reexamining the instant claims, the Examiner has reopened prosecution and a new ground(s) of rejection is made which will be discussed in more detail below.

I. *Response to Arguments/Remarks*

Applicant's amendment, filed February 4, 2008, has overcome the objection of claims 20, 22-33 and 35-37 as containing non-elected subject matter and the rejection of claim 36 under 35 US 112, first paragraph as failing to comply with the enablement requirement. The above objection and rejection have been withdrawn. However, Applicants amendment to claim 35 has not fully overcome the enablement issue. The Examiner will maintain the enablement rejection but change the rejection to a scope of enablement which will be discussed in more detail below.

As mentioned above, upon further examination of the current amendments to the claims, a new ground(s) of rejection is made in view of claims 20, 22-33 and 37 under 35 USC 103 as being unpatentable over *Lefoulon, et al.* (US 6,143,789).

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on February 4, 2008 is in partial compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been partially considered by the examiner.

III. Rejections

35 USC § 103 - OBVIOUSNESS REJECTION

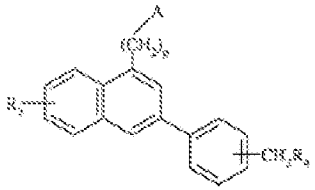
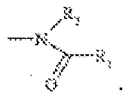
The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). *See Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

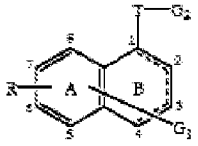
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

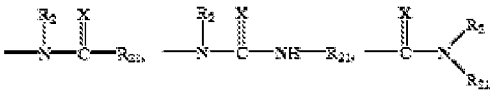
Claims 20, 22-33 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lefoulon, et al.* (US Patent 6,143,789). Applicants claim a compound

of formula  wherein A represents  ; R_1 represents linear or branched (C_1-C_6)alkyl, linear or branched (C_2-C_6)alkenyl, linear or branched (C_2-C_6)alkynyl, (C_3-C_8)cycloalkyl, (C_3-C_8)cycloalkyl-(C_1-C_6)alkyl in which the alkyl moiety may be linear or branched, aryl or aryl-(C_1-C_6)alkyl in which the alkyl moiety may be linear or branched; R_2 represents hydrogen or linear or branched (C_1-C_6)alkyl, it being possible, for R_1 and R_2 together to form a linear or branched alkylene chain having from 3 to 6 carbon atoms; R_3 represents linear or branched (C_1-C_6)alkoxy; R_4 represents halogen, hydroxyl, linear or branched (C_1-C_6)alkoxy or amino optionally substituted by one or two linear or branched (C_1-C_6)alkyl; p is 1,2 or 3; wherein aryl denotes phenyl, naphthyl or biphenyl and the aryl group may be substituted by from 1 to 3 groups selected from linear or branched (C_1-C_6)alkyl, linear or branched (C_1-C_6)alkoxy, hydroxyl, carboxy, formyl, nitro, cyano, linear or branched polyhalo(C_1-C_6)alkyl, alkoxcarbonyl and halogen.

The Scope and Content of the Prior Art (MPEP §2141.01)

Lefoulon, et al. teaches naphthalene derivatives that are melatoninergic receptor ligands. The invention is represented by the general formula:



wherein T represents a linear or branched (C_1-C_6)alkylene chain; A and B together form a naphthalene, dihydronaphthalene or tetrahydronaphthalene group; R represents hydrogen, hydroxy, R' or OR', R' representing an optionally substituted linear or branched (C_1-C_6)alkyl, optionally substituted linear or branched (C_2-C_6)alkenyl, optionally substituted linear or branched (C_2-C_6)alkynyl, optionally substituted (C_3-C_7)cycloalkyl, optionally substituted (C_4-C_7)cycloalkenyl, linear or branched trihalo(C_1-C_6)alkylsulphonyl, optionally substituted aryl, optionally substituted biphenyl or optionally substituted heteroaryl group, or R forms, with two adjacent carbon atoms of the A ring, a 5- to 7-membered ring; G_1 represents a halogen, a linear or branched trihalo(C_1-C_6)alkylsulphonyloxy, carboxy, formyl or cyano group, a radical R_1 or a group –O-CO-R_1; R_1 representing an optionally substituted linear or branched (C_1-C_6)alkyl, optionally substituted linear or branched (C_2-C_6)alkenyl, optionally substituted linear or branched (C_2-C_6)alkynyl, optionally substituted (C_3-C_7)cycloalkyl, optionally substituted aryl, optionally substituted biphenyl or optionally substituted heteroaryl group; G_2 represents a group selected from  ; X represents an oxygen or sulphur atom, R_2 represents a hydrogen atom or a linear or branched (C_1-C_6)alkyl group; R_{21} represents an optionally substituted linear or branched

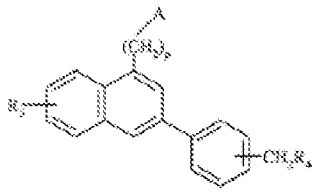
(C_1-C_6)alkyl, optionally substituted linear or branched (C_2-C_6)alkenyl; optionally substituted linear or branched (C_2-C_6)alkynyl, optionally substituted (C_3-C_7)cycloalkyl, optionally substituted heteroaryl, optionally substituted aryl or optionally substituted biphenyl group; wherein the term "optionally substituted" applied to the terms "aryl", "biphenyl" and "heteroaryl" means that those groups are substituted by one or more halogen atoms, and/or linear or branched (C_1-C_6)alkyl, linear or branched trihalo(C_1-C_6)alkyl, hydroxyl, linear or branched (C_1-C_6)alkoxy and/or nitro groups and/or amino groups (optionally substituted by one or two identical or different linear or branched (C_1-C_6)alkyl groups) and/or cyano, carboxy and/or linear or branched (C_1-C_6)alkylcarbonyl groups and/or aminocarbonyl groups.

See also preferred embodiments at columns 4-5 and 7-8, which disclose species teaching specific moieties. Note column 7, lines 4-6 wherein T represents an alkylene chain having 2 or 3 carbon atoms; lines 10-12 wherein G_1 is attached in the 3-position of the bicyclic ring structure or in the 7-position of the same ring structure; lines 13-16 wherein G_1 are optionally substituted aryl (for example phenyl) groups and optionally substituted heteroaryl (for example furyl, thienyl, pyridyl) groups; lines 17-20 R represents a groups R' or OR', wherein R' represents a linear or branched (C_1-C_6)alkyl group (for example a methyl group) or a linear or branched (C_2-C_6)alkenyl group; and lines 21-27 G_2, which correspond to applicants A, wherein X represents an oxygen atom, R_2 represents a hydrogen atom and R_{21} represents a group selected from linear or branched (C_1-C_6)alkyl optionally substituted by one or more halogen atoms, linear or branched (C_2-C_6)alkenyl, linear or branched (C_2-C_6)alkynyl and (C_3-C_7)cycloalkyl.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Lefoulon, et al.* and the instant invention is that there is homologous subject matter. Not all of the substituents are taught, however there is overlap between the substituents disclosed especially in view of the preferred embodiments taught by the prior art. For example, the homologous subject matter is where the substituent on the phenyl ring can be a trihalosubstituted methyl as taught in the prior art whereas the substituent on the phenyl ring in the instant application can be a monohalosubstituted methyl.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)



Applicants are claiming a compound of the formula

wherein specifically R_4 can represent halogen or amino optionally substituted by one or two linear or branched (C_1-C_6)alkyl. The prior art reference of *Lefoulon, et al.* teaches a similar compound wherein the substituents of G_1 (equivalent to the R_4 in the instant application) can be various groups including a linear or branched trihalo(C_1-C_6)alkyl or an amino, optionally substituted by one or two identical or different linear or branched linear or branched trihalo(C_1-C_6)alkyl groups (See column 4, lines 21-34). The prior art reference also teaches two specific compounds, N-{2-[7-methoxy-3-(3-trifluoromethylphenyl)-1-napthyl]ethyl}acetamide wherein G_1 is 3-trifluoromethylphenyl (See column 8, lines 14-15) and N-{2-[7-methoxy-3-(3-aminophenyl)-1-

napthyl]ethyl}acetamide wherein G_1 is 3-aminophenyl (See column 8, lines 16-17).

In In re Hass, 141 F.2d 127, 60 USPQ 548 (CCPA 1944), it was well established that members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed by the prior art. For example, it is obvious to prepare a monohalosubstituted alkyl group (i.e. methyl) when the art teaches a trihalosubstituted alkyl group with a reasonable expectation of success. Further, a monohalosubstituted methyl and a trihalosubstituted methyl are considered homologues and are obvious absent unexpected results. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare adjacent homologs based on the teachings of the preferred embodiments in the prior art absent a showing of unexpected properties. For example, a skilled artisan would be motivated to prepare a 3-phenylnapthalene wherein the phenyl ring is substituted by a monohalosubstituted methyl group instead of a trihalosubstituted methyl group as seen in the prior art reference of *Lefoulon, et al.* (US Patent 6,143,789). A strong prima facie obviousness has been established.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for a method of treating anxiety does not reasonably provide enablement for a method of treating sleep disorders, stress, seasonal affective disorders, cardiovascular pathologies of the digestive system, fatigue due to jet lag, schizophrenia, panic attacks, melancholia, appetite disorders, psychotic disorders, epilepsy, diabetes, Parkinson's disease, senile dementia, disorders associated with normal or pathological aging, migraine, memory loss, Alzheimer's disease, cerebral circulation disorders, sexual dysfunctions and cancer. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue". The factors are applied below to the instant claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The breadth of the claims

The breadth of the claims is a method of treating a living animal body afflicted with a disorder of the melatoninergic system selected from sleep disorders, stress, anxiety, seasonal affective disorders, cardiovascular pathologies, pathologies of the digestive system, insomnia and fatigue due to jetlag, schizophrenia, panic attacks, melancholia, appetite disorders, obesity, insomnia, psychotic disorders, epilepsy, diabetes, Parkinson's disease, senile dementia, disorders associated with normal or pathological aging, migraine, memory loss, Alzheimer's disease, cerebral circulation disorders, sexual dysfunctions and cancer, comprising the step of administering to the living animal body, an amount of the claimed compound.

The nature of the invention

Support for the intended use is based on the melatonin binding study for

melatonin receptors M_1, M_2 and M_3; action of the compounds on the circadian rhythyms of locomotive activity of the rat; anxiolytic activity in rats and activity of the compounds on the caudel artery of the rat (See pages 21-24). Applicants have also submitted a declaration under 37 CFR 1.132 disclosing the various diseases listed in claim 35 can be treated via melatonin receptors.

The state of the prior art and the predictability or lack thereof in the art

As mentioned in Applicants' specification on page 8, compounds of the instant invention have therapeutic properties for the various disorders including sleep disorders, severe depression, Alzheimer's disease, etc. Therefore Applicants' claims a method of treating a living animal body afflicted with a disorder of the melatoninergic system including Alzheimer's disease, cardiovascular pathologies, psychotic disorders, diabetes, migraine, etc.

The state of the prior art, for example, is that the treatment of Alzheimer's disease, for example, remains highly unpredictable. It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease. (<URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html>.)

In addition, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents (*See* e.g., the Cecil Textbood of Medicine, 20th edition (1996), Vol. 2, page 1994). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

Applicants' claim is also drawn to a method of treating cancer. The above conditions embrace various types of cancer. The state of the prior art is that cancer therapy remains highly unpredictable. The various types of cancers have different causative agents, involve different cellular mechanisms, and consequently, differ in treatment protocol. Cancer is a disease characterized by a population of cells that grow and divide without respect to normal limits, invade and destroy adjacent tissues, and may spread to distant anatomic sites through a process called metastasis (URL:http://en.wikipedia.org/wiki/ Cancer>). Most cancers are named for where they start. For example, lung cancer starts in the lung, and breast cancer starts in the breast. Symptoms and treatment depend on the cancer type and how advanced it is (URL: <http://www.nlm.nih.gov/medlineplus/cancer. html>>). It is known that the challenge of cancer treatment has been to target specific therapies to pathogenetically distinct tumor types, that cancer classification has been based primarily on morphological appearance

of the tumor and that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy (Golub et al. page 531). Treatment may include surgery, radiation, chemotherapy, immunotherapy, monoclonal antibody therapy, etc. Furthermore, it is known that chemotherapy is most effective against tumors with rapidly dividing cells and that cells of solid tumors divide relatively slowly and chemotherapy is often less effective against them. It is also known in the prior art (Lala et al. page 91) that the role of NO in tumor biology remains incompletely understood with both the promotion and inhibition of NO mentioned for the treatment of tumor progression and only certain human cancers may be treated by selected NO-blocking drugs. These example shows that there are different cellular mechanisms, the unpredictability in the art and the different treatment protocols. Because "cancer" refers to a class of diseases, it is unlikely that there will ever be a single "cure or treatment for cancer".

Applicants' declaration under 37 CFR 1.132 has been considered but is not enough evidence to convince the Examiner that the novel compounds of the instant invention can treat all of the various diseases disclosed. Especially, as discussed above it is difficult treat several of the diseases such as Alzheimer's disease and cancer. According to Li, et al. (Drugs of the Future 2000, 25(9) page 948), the effects of melatonin in oncogenesis and the effects of melatonin in relation to cancer within the body are unclear. This shows that a definitive conclusion between the effects of melatonin in relation to cancer has not been drawn and more experimentation is required. The Examiner also wants to point out that the Skene, et al. reference (Brain

Research, 1990, 528, pages 170-174) disclosed in Applicants declaration does not show that melantonin can be used to treat Alzheimer's disease. This reference discloses that "Patients who had Alzheimer's disease had significantly reduced melatonin levels during the night compared with the non-Alzheimer group". The reference further discloses that "when more accurately age-matched controls were compared with the Alzheimer subjects, no differences between the two groups were observed." This reference that was submitted by Applicants and disclosed in the declaration does not provide support that the novel compounds of the instant invention can be used to treat Alzheimer's disease.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can be used to treat all of the embraced melatoninergic disorders. Applicants have not provided enough competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating all conditions by administering the instant claimed compounds. However, Applicants have disclosed several tests such as an anxiolytic activity assay, a locomotive activity assay and an assay that demonstrates vasoconstriction or vasodilation of the caudal artery. Therefore, Applicants are enabled for the treatment of anxiety since Applicants have provided data showing the compounds having anxiolytic activity (pages 23-24).

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claim.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

Applicants can overcome the above rejection by, for example, limiting the method claim to treating anxiety.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Specifically, Applicants are claiming broad classes of diseases and have failed to define these broad classes in the specification so that one of ordinary skill in the art would know what diseases are embraced by the broad classes. The broad classes of diseases are "sleep disorders", "cardiovascular pathologies", "pathologies of the digestive system", "appetite disorders", "disorders associated with normal or pathological aging", “cerebral circulation disorders”, “sexual dysfunctions” and “cancer”. Therefore, the claim is indefinite.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 35

recites the broad recitation sleep disorders and the claim also recites insomnia which is the narrower statement of the range/limitation.

IV. *Objections*

Claim Objection-Non Elected Subject Matter

Claim 20 is objected to as containing non-elected subject matter, specifically the term “heteroaryl” (See page 2, lines 2-4). To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

V. *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{c}Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/
Examiner, Art Unit 1626

/Joseph K McKane/

Supervisory Patent Examiner, Art Unit 1626